

REMARKS

Claims 1-45 were presented for examination. Claims 18-21, 29-32, and 43-45 are non-elected claims. Claims 1-17, 22-28, and 33-42 are rejected. Applicants hereby amend claims 1, 22, 33, and 34, and add new claims 46-48. Applicants believe that no new matter has been added. Support for the claim amendments can be found throughout the specification as originally filed including, for example, paragraph 25 on pages 5-6 of the specification and claims 4-5 as originally filed. Support for the new claims can be found throughout the specification as originally filed including, for example, paragraph 45 on page 12.

A complete list of all claims is attached herewith in Appendix A.

**Rejection of Claims 1-3, 9-17, 22-23, 26-28, 33-35,
and 37-42 Under 35 U.S.C. § 102(b)**

Claims 1-3, 9-17, 22-23, 26-28, 33-35, and 37-42 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,110,484 to Sierra ("Sierra "). The Office Action states that Sierra discloses biomedical implants having resorbable particles embedded within a resorbable matrix where the particles degrade faster than the matrix in which they are implanted to form pores within the matrix. The Office Action further states that the size of the particles and the ratio of particles by volume are within the instant claimed range.

Sierra discloses a biomedical implant comprising a biomedical matrix material and a biodegradable porosifying agent. As the porosifying agent degrades in situ, an implant with an inter-connecting network is formed. The resultant mechanically stable implant allows for tissue and fluid influx into the matrix.

Applicants respectfully submit that amended claims 1, 22, 33, and 34 are novel over Sierra under 102(b). Amended claims 1, 22, 33, and 34 each recites "a bioresorbable bulk material comprising an ionically or covalently crosslinked polymeric material." The Examiner appears to agree that Sierra does not teach "the manner in which the matrix is cross-linked (i.e., covalent or ionic)." Office Action page 4, para. 12.

Therefore, Applicant respectfully submits that amended claims 1, 22, 33, and 34 and all claims dependent therefrom are patentable over Sierra under 35 U.S.C. §102(b).

Rejection of Claims 4-8, 24-25, and 36 Under 35 U.S.C. § 103(a)

Claims 4-8, 24-25, and 36 are rejected under 35 U.S.C. § 103(a) as being rendered obvious by Sierra in view of U.S. Patent No. 6,060,534 to Ronan *et al.* ("Ronan"). The Office Action states that Sierra does not teach "the manner in which the matrix is cross-linked (i.e., covalent or ionic) nor the specific polymers of the instant claims." Office Action page 4, para. 12. The Office Action, however, asserts that it would have been obvious to one skilled in the art at the time of the invention to combine the teachings of Ronan and Sierra.

Ronan discloses shaped medical devices having improved mechanical properties and structural integrity. The devices comprise shaped polymeric hydrogels which are both ionically and non-ionically crosslinked and which exhibit improved structural integrity after selective removal of the crosslinking ions. When implanted in the body, selective in-vivo stripping of the crosslinking ions produces a softer, more flexible implant having improved structural integrity.

Amended claims 1, 22, 33, and 34 each recites "a bioresorbable bulk material comprising an ionically or covalently crosslinked polymeric material." Ronan discloses ionically and non-ionically crosslinked polymeric hydrogels. When implanted in the body, the Ronan devices are selectively stripped of the crosslinking ions to produce a softer, more flexible implant with improved structural integrity. Ronan does not teach or suggest an ionically or covalently crosslinked polymeric material for use as a bioresorbable bulk material in a medical device that displays controlled resorption rate. Ronan teaches a method of adjusting *in vivo* the flexibility of an implant. It does not teach a method of adjusting the *in vivo* resorption rate.

In addition, there is no teaching or suggestion in Sierra that crosslinked polymeric materials are preferable over the materials disclosed therein for use as the bioresorbable bulk material. There is no motivation for a person of ordinary skill in the art to look for crosslinked polymeric materials for use in the Sierra devices. Sierra teaches a method of introducing porosity into a biomedical matrix as compared to the controlling of resorption rate of the bioresorbable bulk material. Furthermore, there is no reasonable expectation that the ionically or covalently crosslinked polymeric materials disclosed in Ronan would be successfully adapted to the use disclosed in Sierra. Therefore, an ordinary skilled person lacks (1) a motivation to look for the teachings of Ronan to combine with that of Sierra and (2) a reasonable expectation that the Ronan teachings could be successfully applied to the method of Sierra.

Therefore, Applicants respectfully submit that amended claims 1, 22, 33, and 34 and all claims dependent therefrom are patentable over Sierra and Ronan, individually or in combination, under 35 U.S.C. §103(a).

5

Conclusion

Applicants respectfully request that the Examiner reconsider the rejections in light of the foregoing amendments and remarks, and respectfully submit that amended claims 1, 22, 33, and 34, and all pending claims depending therefrom are in condition for allowance. The Examiner is kindly invited to contact the undersigned at (617) 248-7809 or zhangy@tht.com to discuss any
10 outstanding issues in this case.

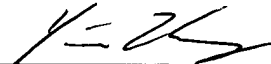
Respectfully submitted,

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Date: August 19, 2003

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